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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,496	10/31/2003	Steven L. Jacques	1233-030 NP	9597

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EXAMINER
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NGUYEN, TUAN VAN

ART UNIT	PAPER NUMBER
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3731

MAIL DATE	DELIVERY MODE
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05/07/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/698,496	<b>Applicant(s)</b> JACQUES, STEVEN L.	
	<b>Examiner</b> TUAN V. NGUYEN	<b>Art Unit</b> 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 January 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 14-19, 22-24 and 26-33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 14-19, 22-24 and 26-33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 October 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### ***DETAIL ACTION***

1. In previous Office action, claims 14-19, 22-24 and 26-31 were examined and rejected.
2. This Office action is in response to the amendment filed on 1/23/2009.

### ***Response to Arguments***

3. In page 6 of the Remarks, Applicants argue that Sadamasa fails to disclose the limitation of “the lumen spaced apart from one another by a predetermined distance” because the distance a lumen is spaced apart from another lumen as shown in Fig. 9B of the instant application is not the distance between the centers of two lumens, as interpreted is incorrect. Noting that the distance 114 and 128 as shown in Fig. 9B of the instant application describe **the distance between the periphery of one lumen to the periphery of another lumen**. Here it is noted that the limitations on which the Applicant relies are not stated in the claims. It is the claims that define the claimed invention, and it is claims, not specifications that are anticipated or unpatentable. *Constant v. Advanced Micro-Devices Inc.*, 7 USPQ2d 1064. The limitation of “the lumen spaced apart from one another by a predetermined distance” it can be interpreted, in its broadest sense, as the distance between a center of one lumen to the center of another lumen. Extrinsic evidence, Jackson (US 4850969) discloses (Fig. 2) a plurality of holes 31 are spaced apart by a suitable distance on centers (col. 3, lines 55-60).

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. **Claims 14-19, 22-24 and 26-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sadamasa (U.S. 6,017,339) in view of Richardson (U.S. Pub. No. 2003/0078473) further in view of Howell et al (US 6,740,277).**

7. Referring to **claims 14-16, 19, 23-24 and 26-33**, Sadamasa discloses (see Figs. 2, 3, and 4) a catheter device comprising: a shaft 15 having proximal end and distal end; a distal terminus 15b, one lumen 17b for receiving guide wire; one lumen 17a for cutting wire 20; wherein the cutting wire is exiting a hole 19b then entering the second hole 19a and the distal tip of cutting wire is anchor by anchoring member 35; the thirds lumen 17c; and the lumens spaced apart from

one another by a predetermined distance in the untapered length (Fig. 3A), a corresponding distance between the lumens in the tapered portion being different from the predetermined distance in the untapered portion (Fig. 2, at the distal tip marked 15b, the diameter of lumens are smaller than the diameter at the untapered portion, thus, the distance between the center of one lumen to the center of another lumen at the distal tip is smaller compare to the distance between the center of one lumen to the center of another lumen at the untapered portion (col. 5, line 65 to col. 6, line 65). Sadamasa discloses the distal tip should has tapered configuration so as to be easily inserted (col. 6, lines 32-35) except for specifically disclosing the length of the taper portion of the tip is approximately 3 mm or less and the distal terminus has an outer diameter less than approximately 0.063 inch.

8. Still referring to **claims 14-16, 19, 23-24 and 26-33**, however, Richardson discloses a biliary catheter (see Fig. 3) having a tapered distal tip wherein the length of the tapered tip is about 0.10 cm (1 millimeter) to 5.0 cm (50 millimeters) for the purpose increase the probability of initially getting into a smaller opening such as the orifice of Vater (see paragraph [0038]-[0039]). However, Richardson fails to discloses the distal terminus has an outer diameter less than approximately 0.063 inch.
9. Still referring to **claims 14-16, 19, 23-24 and 26-33**, however, Howell discloses a method of making a tapered tip for a catheter wherein the design intended of the tapered tip is for facilitating the insertion of the catheter into a vessel and to avoid

discomfort and tissue trauma to the patient (see col. 1, lines 50-55). Howell also discloses the outer diameter of catheter may have a diameter of 0.020 to 0.140 inches (see col. 5, lines 35-43) and the tapered tip may have a configuration according to US Patent No. 4,588,398 (see col. 4, lines 38-45). Now, turning to US Patent No. 4,588,398 issued to Daugherty et al. Figure 1 of Daugherty's drawings discloses a catheter having a tapered tip configuration that includes the length of the tapered portion and outer diameter of the terminus (see col. 3, line 25 to col. 4, lines 50). Since it has been held that use of known technique to improve similar devices in the same way and applying a known technique to a known device ready for improvement to yield predictable results are old and well known in the art, therefore, it would have been obvious to one of ordinary skill in the art to use the desired of increase the probability of initially getting into a smaller opening such as the orifice of Vater as suggested by Richardson and teaching of how to make a tapered tip catheter as suggested Howell to modify the tip of Sadamasa catheter so that it too would have the same advantage. With respect to the dimensions that that claimed by the applicant, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

10. Referring to **claims 17 and 18**, Sadamasa discloses and endoscopic diathermic knife (see Fig. 2) for performing endoscopic papillotomy or sphincterotomy (see Background of The Invention) having a radiopaque marker 21 at the distal of the

cutting wire 16a and inside the lumen of the cutting wire for the purpose of visually locating the location of the distal tip (see col. 6, lines 18-32).

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TUAN V. NGUYEN whose telephone number is (571)272-5962. The examiner can normally be reached on M-F: 9:00 AM - 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, AnhTuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3731

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/T. V. N./  
Examiner, Art Unit 3731

/Anhtuan T. Nguyen/  
Supervisory Patent Examiner, Art Unit 3731  
5/5/09